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LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160				LANDSMAN, ROBERT S
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/703,253

Filing Date: October 31, 2000

Appellant(s): HARRAS ET AL.

**MAILED**  
**AUG 22 2006**  
**GROUP 1600**

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Peter Seferian  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 6/8/06 appealing from the Office action mailed 5/5/03.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

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The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The amendment after final rejection filed on 4/23/03 has been entered.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Vukicevic et al. 'Induction of nephrogenic myosenchyme by osteogenic protein 1 (bone morphogenetic protein 7).' PNAS USA 93:9021-9026, 1996.

Massague J. "The TGF-B Family of Growth and Differentiation Receptors." Cell 49:437-8, 1987.

Pilbeam et al. "Comparison of the Effects of Various Lengths of Synthetic Human Parathyroid Hormone-Related Peptide (hPTHrP) of Malignancy on Bone Resorption and Formation in Organ Culture." Bone 14:717-720, 1993.

Skolnick, J. et al "From genes to protein structure and function:novel applications of computational approaches in the genomic era." Trends in Biotech, vol 18, no. 1 (2000), pp. 34-39

Bork, P. "Powers and pitfalls in sequence analysis:the 70% hurdle." Genome Research, vol. 10 (2000), pp. 398-400.

Doerks, T, et al. "Protein annotation:detective work for function prediction." Trends in Genetics, vol 14, No. 6 (June 1998), pp. 248-250.

Smith, TF, et al. "The challenges of genome sequence annotation or "the devil is in the details." Nature Biotechnology, vol. 15 (November 1997), p. 1222-1223.

Brenner, SE. "Errors in genome annotation." Trends in Genetics, vol. 15, No. 4 (April 1999), p. 132.

Bork, P. et al. "Go hunting in sequence databases but watch out for the traps." Trends in Genetics, vol. 12, No. 10 (October 1996), pp. 425-427.

Suzuki T. et al., "cDNA Cloning of a Short Type of Multidrug Resistance Protein Homologue, SMRP, from a Human Lung Cancer Cell Line." Biochem. Biophys. Res. Comm. 238(3):790-794, 1997.

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

##### **A. Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 1 and 5-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well established utility. These claims are drawn to an invention with no apparent or disclosed patentable utility. This rejection is not in conflict with the current utility guidelines. The instant application has provided a description of a partially isolated protein. However, the instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the claimed receptor is termed an "orphan receptor" in the art and only teaches that this protein is *homologous* to NKAF polypeptides. There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete.

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The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed “real-world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility,” “[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field,” and “a patent is not a hunting license,” “[i]t is not a reward for the search, but compensation for its successful conclusion.”

The instant claims are drawn to a protein which has a yet undetermined function or biological significance. Applicants have disclosed that they are in possession of compounds which *bind* this receptor, however, there is no actual and specific significance which can be attributed to said protein identified in the specification. For this reason, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a “real-world” use for said protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

**Therefore, since the protein of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the polynucleotides, vectors, host cells and methods of producing the host cells and proteins also are not supported by a specific and substantial asserted utility or a well established utility.**

#### ***B. Claim Rejections - 35 USC § 112, first paragraph - enablement***

A. Claims 1 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

**(10) Response to Arguments****A. Claim Rejections - 35 USC § 101**

Appellants argue that the specification details a number of specific and substantial utilities for the presently claimed polynucleotide sequences which encode a novel isoform of an ATP-binding cassette transporter protein, a class of proteins that are well known to be involved in mammalian multi-drug resistance. The specification details a number of uses for the presently claimed polynucleotide sequences, including the detection and diagnosis of human disease as well as to therapeutically augment the efficacy of chemotherapeutic agents used in the treatment of breast or prostate cancer. The sequences of the present invention are noted to be expressed in prostate. Additional uses include assessing temporal and tissue-specific gene expression patterns, particularly using a high throughput "chip" format, mapping the sequences to a specific region of a human chromosome and identifying protein encoding regions and determining the genomic structure. As a still further example of utility is the use of the present sequences in such diagnostic assays as those associated with identification of paternity and forensic analysis, among others. The sequences of the present invention have particular utility as the application as filed identified several polymorphisms.

These arguments have been considered, but are not deemed persuasive. These arguments do not demonstrate a "specific or substantial utility" for the claimed nucleic acid molecules, or encoded proteins. Appellants provide Accession No. NP\_115972 (Tammur et al.) which is 88% identical to SEQ ID NO:23 of the present invention and Accession No. NP\_660187 (Turriziani et al.) which is 85% identical. Appellants argue that the nucleic acid molecule of the present invention is 94% identical to the polynucleotides encoding these Accession Nos.

First, it is noted that the polypeptides of Tammur et al. and Turriziani et al. both have a stretch of approximately 160 additional amino acids not found in SEQ ID NO:23. Therefore, the polypeptide of SEQ ID NO:23 is "lacking" a large section of the polypeptides of Tammur et al. and Turriziani. As seen on pages 5-6 of the Office Action mailed 12/19/01, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein. Therefore, based on these teachings in the art, it would not be expected that a polypeptide "lacking" 160 residues as compared to a similar polypeptide would have the same function as that in the art. Furthermore, due to the large number of distinct ABC subclasses (at least up to ABC11), it can not be convincingly accepted based solely on homology that a protein lacking as large a region as SEQ ID NO:23 would not fall into another subclass of ABC receptor than that of Tammur or Turriziani.

Furthermore, the utility of ABC transporters is to transport various compounds, or families of compounds, from cells. As seen in the post-filing paper of Tammur et al. (Abstract; Gene 273:89-96, 2001), the ABC superfamily of transporters is currently comprised of three different transporter types, the MDR-like, sulfonylurea receptor, and CFTR gene and the phylogenetic analysis of these transporters further divides these transporters into seven subfamilies (first paragraph of the Introduction, page 89). In fact, Tammur et al. teach that their MDR gene (ABCC11), which Appellants argue is similar to SEQ ID NO:23 of the present invention, is most similar to ABCC5 (page 94, left column, second full paragraph) and that ABCC5 confers resistance to PMEA (page 93, right column, first paragraph). However, Tammur et al. teach that no difference was seen in expression levels of ABCC11 between the parental and PMEA-resistant cell lines, demonstrating that even though ABCC11 is closely related to ABCC5, the function of ABCC11 cannot be predicted based on the function of ABCC5. Therefore, in addition to the polypeptide of the present invention only showing 88% identity to that of Tammur et al., Appellants have also not identified which types, or families, or drugs are transported by the proteins of the present invention, as this cannot be predicted by sequence homology to known ABC transporters, further making the present invention incomplete.

Appellants further argue that there is an entire industry based on the use of gene sequences, or fragments thereof in gene chip and non-gene chip format. Appellants argue that the existence and acquisition of companies in this industry, as well as projects such as the Human Genome Project, demonstrate a substantial utility, which is well-established. Appellants argue that the present nucleotide sequences clearly encode a novel human transporter and, therefore, that the present sequences are specific markers of the human genome which are targets for the discovery of drugs that are associated with human diseases and even that "negative information" has a great "real-world" practical utility.

The specification does not disclose any function, nor any dysfunction, associated with altered levels or forms of the nucleic acid molecules of the present invention. Therefore, knowing the chromosomal location of the claimed nucleic acid molecule would not provide a well-established utility under the meaning of 35 USC 101. Significant further experimentation would be required to identify an dysfunction or disease associated with the claimed nucleic acid molecules. There is no disclosure, for example, of any symptoms associated with such a disease or dysfunction of these molecules. Additionally, the use of nucleic acid molecules of the present invention in gene/non-gene chip technologies, or to analyze gene expression is not a specific or substantial utility since any nucleic acid molecules can be used for this purpose. In addition, the tissues shown to express these nucleic acid molecules have not been shown to be specific for the nucleic acid molecules of the present invention.

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Appellants conclusion from this is that “those skilled in the art would clearly believe that Appellants’ sequence is a novel human isoform of the ATP-binding cassette, sub-family C, member 11; multi-resistance protein 8.” On page 5 of the Brief, Appellants also reference MDRs described in issued U.S. Patents Nos. 5,198,344 and 5,866,699 and argue that “[t]he application as filed clearly describes the current invention as a novel human transporter protein and the function of transporter proteins as integral membrane proteins that mediate or facilitate the passage of materials across the lipid bilayer and identifies their role as a mechanism of drug resistance wherein diseased cells using cellular transporter systems to export chemotherapeutic agents from the cell and later in the specification asserts a utility in augmenting the efficacy of chemotherapeutic agents used in the treatment of breast or prostate cancer. While this is not conceded by the Examiner that the present protein is, in fact, as argued by Appellants due to the fact that a large portion of the protein of the present invention is not found in the ABC11 proteins of the cited art even, arguendo, the protein of the invention was shown to be as Appellants claim, Appellants’ specification did not disclose the protein as this exact member of the ABC family. All that was disclosed is that the protein is believed to be an MDR protein. Appellants have not shown that the protein of the invention can be used to treat, e.g., prostate cancer. It is only suggested.

Appellants further argue that Tammur, Yabauuchi and Turriziani discuss the roles (utility) and importance of their cloned ABC transporters. Again, the Examiner does not question these findings. The issue is whether or not the protein of the invention is, in fact, a member of the same subfamily as those of the references and whether or not the protein can be used in the treatment of the disclosed diseases (e.g. prostate cancer).

Appellants further argue the use of gene chips, DNA as specific markers and diagnostic assays such as identifying polymorphisms and forensic analysis. Though the DNA of the present invention can be used in gene chip technology, it is not the individual DNA which possesses utility, but the collection of DNA as a whole. While Appellants may argue that each gene is important in providing an overall picture, and while the invention of the gene chip, itself, may possess utility, this is still not sufficient to establish utility of individual polynucleotides under the meaning of 35 USC 101. Appellants argue that “by identifying the physiological activity role of the claimed sequence, the claimed sequence has a far greater utility in gene chip applications than just any random piece of DNA.” This, however, is the issue. The Examiner’s position is that the DNA of the present invention is, in fact, a “random piece of DNA” with only homology to known proteins.

Furthermore, the use of DNA as a diagnostic is credible and specific, however, it is not substantial. The specification does not disclose any function, nor any dysfunction, associated with altered

levels or forms of the polypeptide encoded by SEQ ID NO:23. Appellants only make an association based on homology to known ABC proteins. Significant further experimentation would be required of the skilled artisan to identify a dysfunction or disease associated with the claimed polypeptide. There is no disclosure, for example, of any symptoms associated with such a disease or dysfunction of the polypeptide. Since this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. In addition, while it may be interesting that the DNA of the invention has polymorphisms and can be used in forensics, this still does not provide specific and substantial utility to the DNA. Identifying a polymorphism does not tell us what the function is of the polynucleotide/polypeptide. Even if the polymorphism could be used as a marker to distinguish 50% of the population, it does not tell us how to use the claimed polynucleotide. Again, no symptoms associated with such a disease or dysfunction of the polypeptide have been disclosed.

Appellants further argue that e.g. all batteries, tires, etc. have utility. While this may be true, the definition of "utility" in the general sense is not the same as that defined under 35 USC 101. Simply because a pen is useful does not mean that an inventor can create a pen and patent it. Inventors are not able to receive patents for these inventions unless there is some new or improved aspect of the current product on the market. In addition, we know what the utility of batteries, tires, etc. are. Appellants have not provided such information regarding the DNA of the present invention.

Appellants further argue that "the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequence." This argument has been considered, but is not deemed persuasive since Appellants have not taught that the DNA (gene) of the invention is associated with a disease state. While this specificity may be unique it is not substantial in its present form, nor is it specific under 35 USC 101.

Finally, the argument that the presently described cDNA's provide biologically validated empirical data is also not persuasive since this is not a specific utility of this cDNA compared to the thousands of DNA molecules that encode thousands of potentially unrelated proteins.

It is believed that all pertinent arguments have been addressed.

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**B. 35 USC § 112, first paragraph - enablement**

A. Claims 1 and 5-7 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 12/18/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Robert Landsman

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